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10/682,067

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EXAMINER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MARK B. KNUDSON and WILLIAM L. GIESE

Appeal 2010-005226
Application 10/682,067
Technology Center 3700

Before: JENNIFER D. BAHR, STEVEN D. A. MCCARTHY, and FRED
A. SILVERBERG, *Administrative Patent Judges*.

BAHR, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Mark B. Knudson and William L. Giese (Appellants) appeal under 35 U.S.C. § 134 from the Examiner's rejection of claims 16, 18-22, 24, 31, 33-36, 38-41, 43-45, 47-51, 53-62, and 64 under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as being unpatentable over Lazarus (US 4,787,899, iss. Nov. 29, 1988); claims 16, 18-22, 24, 31, 33-36, 38-41, 43-45, 47-51, and 53-62 under 35 U.S.C. § 103(a) as being unpatentable over Lazarus and either Robinson (US 4,604,762, iss. Aug. 12, 1986) or Lee (US 5,123,917, issued Jun. 23, 1992); and claims 37, 46, and 63 under 35 U.S.C. § 103(a) as being unpatentable over Lazarus and Bowen (US 2,127,903, iss. Aug. 23, 1938), or Lazarus and either Robinson or Lee, further in view of Bowen. Claims 1-15, 26-30, 32, 42, and 52 have been canceled. The Examiner has withdrawn claims 17, 23, and 25 from consideration. We have jurisdiction under 35 U.S.C. § 6(b).

SUMMARY OF DECISION

We REVERSE.

THE INVENTION

The claims are directed to an apparatus for performing coronary artery bypass surgery. Spec. 1:13. Claim 16, reproduced below, is illustrative of the claimed subject matter.

16. A bypass conduit for use in a wall of a heart, comprising:

a hollow conduit having an interior and an exterior and adapted to be positioned in the heart wall between a coronary vessel and a chamber in the heart, wherein the conduit has an attachment mechanism on at least one end adapted to anchor the conduit in place,

wherein the conduit is sufficiently rigid such that a pathway between the coronary vessel and the chamber defined by the conduit remains open during both systole and diastole.

OPINION

Independent claims 16 and 22 are directed to a “bypass conduit for use in a wall of a heart” and require the conduit to be “adapted to be positioned in the heart wall between a coronary vessel and a chamber in the heart.” Claim 24 is directed to a “conduit for placing a coronary vessel of a patient’s heart in communication with a heart chamber” and requires a tubular element “configured to be positioned in the wall of a patient’s heart.”

A dispositive issue in this appeal is whether the Examiner has established a *prima facie* case either that a graft obtained by following the teachings of Lazarus necessarily would have dimensions sufficient for the graft to be adapted to be positioned in the wall of a heart between a coronary vessel and a chamber of the heart, as called for in Appellants’ claims or, in the alternative, that it would have been obvious to modify the graft of Lazarus so as to have such dimensions.

Appellants argue, *inter alia*, that “[a] graft pursuant to the teachings of Lazarus will not have suitable dimensions for placement in the heart wall between a coronary vessel and a chamber in the heart. In particular, the graft will not have a length and a diameter suitable for myocardial placement.” App. Br. 5.

In response, the Examiner asserts that “[t]he properties that are inherent in the conduit of Lazarus would equally allow for its placement in the heart wall between a coronary vessel and a chamber in the heart.” Ans. 8. The Examiner further contends that any difference between the

dimensions of Lazarus' graft and dimensions having the necessary relationship to the relevant cardiac dimensions to render the graft usable for cardiac implantation are "irrelevant, as it is directed towards an intended use." Ans. 9.

The Examiner's second point is not entirely accurate. While Appellants' claims do not explicitly recite any dimensions, even by reference to specific anatomical cardiac dimensions, Appellants' claims do, as pointed out above, require a conduit that is suitable for use as a bypass conduit, or a "conduit for placing a coronary vessel of a patient's heart in communication with a heart chamber," and configured to be positioned in the wall of a patient's heart. Any graft or implant that does not have the required dimensions to render it capable of such use does not satisfy the requirements of Appellants' claims.

The Examiner appears to be relying on the theory of inherency to establish that the implant of Lazarus has the required dimensions to render it capable of the use called for in the claims. "It is well settled that a prior art reference may anticipate when the claim limitations not expressly found in that reference are nonetheless inherent in it. Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates." *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349 (Fed. Cir. 2002) (citations and internal quotation marks omitted). "Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (citations and internal quotation marks omitted). When relying on the theory of inherency, the examiner has the initial burden of providing a basis in fact and/or technical reasoning to

reasonably support the determination that the allegedly inherent characteristic reasonably flows from the teachings of the applied prior art. *See In re King*, 801 F.2d 1324, 1327 (Fed. Cir. 1986). Only after the examiner has discharged that initial burden does the burden shift to the applicant to prove that the prior art does not possess the characteristic at issue. *Id.* In our opinion, the Examiner has not discharged that initial burden.

The Examiner has not pointed to any teaching in Lazarus that might support the Examiner's position that the properties, including dimensions, that are inherent in the conduit of Lazarus would equally allow for its placement in the heart wall between a coronary vessel and a chamber in the heart for serving as a bypass conduit or for placing a coronary vessel of a patient's heart in communication with a heart chamber, as called for in Appellants' claims.

We find that Lazarus discloses an artificial intraluminal graft device for placement within a corporeal lumen, such as a blood vessel or artery, for repair of a vital lumen, such as the aorta. Col. 1, ll. 11-12, 20-21; col. 2, ll. 12-13. Lazarus does not discuss use of the disclosed intraluminal graft device as a coronary bypass conduit or placement of the device in the wall of a heart. Further, Lazarus does not specify numerical dimensions for the intraluminal graft. Lazarus teaches that the length of the graft is selected by the user and typically will be longer than the diseased portion of the lumen to be repaired. Col. 4, ll. 14-17. Lazarus also teaches that the radial or cross-sectional size is also selected by the user and typically will substantially conform to or be slightly larger than the interior cross-section of the involved lumen. Col. 4, ll. 17-20.

Based on our findings above, we cannot find by a preponderance of the evidence that a graft obtained by following the teachings of Lazarus necessarily would have dimensions sufficient for the graft to be adapted to be positioned in the wall of a heart between a coronary vessel and a chamber of the heart, as called for in Appellants' claims. Accordingly, the Examiner has failed to establish a prima facie case that Lazarus anticipates the subject matter of claims 16, 22, and 24, and their dependent claims.

In articulating the "alternative" position on page 6 of the Answer, the Examiner has not articulated any reason why it would have been obvious to modify the graft of Lazarus so as to have the necessary dimensions to be adapted to be positioned in the wall of a heart between a coronary vessel and a chamber of the heart, as called for in Appellants' claims. Accordingly, the Examiner has not established a prima facie case that Lazarus renders obvious the subject matter of claims 16, 22, 24, and their dependent claims.

For the above reasons, we reverse the Examiner's rejection of claims 16, 18-22, 24, 31, 33-36, 38-41, 43-45, 47-51, 53-62, and 64 under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as being obvious in view of Lazarus.

In rejecting claims 16, 18-22, 24, 31, 33-36, 38-41, 43-45, 47-51, and 53-62 under 35 U.S.C. § 103(a) as being unpatentable over Lazarus and either Robinson or Lee, and claims 37, 46, and 63 under 35 U.S.C. § 103(a) as being unpatentable over Lazarus and Bowen, or Lazarus and either Robinson or Lee, further in view of Bowen, the Examiner does not articulate any reason why it might have been obvious to modify the graft of Lazarus to overcome the deficiency noted above. Consequently, we reverse these rejections as well.

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Application 10/682,067

DECISION

For the above reasons, the Examiner's decision is reversed.

REVERSED

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